

class 1-8, 10, 14, 15, 17, 18 must choose one stiffness level
off. filing date: 25-30, 37-39, 42-43 choose one crossing angle
01/04/2002 1-8, 10, 14, 15, 17, 18, 25-30
What is claimed is: Groups: prosthesis process for fabricating

✓ 1. A body insertable prosthesis, including:
a body insertable tubular structure including at least one flexible strand selectively formed to provide a plurality of discrete tubular segments including a first segment, a second segment spaced apart axially from the first segment, and a third segment disposed between the first and second segments;

wherein each of the segments has a nominal diameter when the tubular structure is in a relaxed state and is radially compressible against an elastic restoring force to a predetermined diameter;

wherein the at least one flexible strand further is selectively configured to provide first, second and third axial stiffness levels and first, second and third radial force levels along the first, second and third segments, respectively, when said segments are radially compressed to the predetermined diameter; and

wherein the third axial stiffness level is outside of a range of axial stiffness levels bound by the first and second axial stiffness levels.

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- ✓ 2. The prosthesis of claim 1 wherein:
the first and second axial stiffness levels are substantially the same.
- ✓ 3. The prosthesis of claim 1 wherein:
the first and second axial stiffness levels are less than the third axial stiffness level.
- ✓ 4. The prosthesis of claim 1 wherein:
the first and second axial stiffness levels are higher than the third axial stiffness level.
5. The prosthesis of claim 1 wherein:
the at least one flexible strand includes a plurality of flexible strands helically wound in opposite directions to form multiple strand crossings defining strand crossing angles, including respective first, second and third strand crossing angles along the first, second and third segments, respectively; and

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the third strand crossing angle is outside of a range of strand crossing angles bound by the first and second strand crossing angles.

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6. The prosthesis of claim 5 wherein:

the third strand crossing angle is larger than the first and second strand crossing angles, and the third axial stiffness level is less than the first and second axial stiffness levels.

7. The prosthesis of claim 5 wherein:

the third strand crossing angle is smaller than the first and second strand crossing angles, and the third axial stiffness level is higher than the first and second axial stiffness levels.

8. The prosthesis of claim 1 wherein:

the third radial force level is outside of a range of radial force levels bound by the first and second radial force levels.

9. The prosthesis of claim 8 wherein:

the third axial stiffness level is higher than the first and second axial stiffness levels, and the third radial force level is higher than the first and second radial force levels.

10. The prosthesis of claim 8 wherein:

the third axial stiffness level is higher than the first and second axial stiffness levels, and the third radial force level is lower than the first and second radial force levels.

11. The prosthesis of claim 1 wherein:

the at least one strand incorporates a first number of filaments along a first region of the tubular structure and incorporates a second number of filaments, less than the first number, along a second region of the tubular structure; and

one of the first and second regions includes the first and second segments, and the other of said regions includes the third segment.

12. The prosthesis of claim 11 wherein:

the first region includes the first and second segments, whereby the first and second axial stiffness levels are higher than the third axial stiffness level and the first and second radial force levels are higher than the third radial force level.

13. The prosthesis of claim 11 wherein:

the first region includes the third segment, whereby the third axial stiffness level is higher than the first and second axial stiffness levels, and the third radial force level is higher than the first and second radial force levels.

14. The prosthesis of claim 1 wherein:

the tubular structure consists essentially of an alternating series of segments having relatively high axial stiffness levels and segments having relatively low axial stiffness levels, said alternating series including the first, second and third segments.

15. The prosthesis of claim 14 wherein:

each of the segments of the alternating series has an axial length of at least about 1 cm.

16. The prosthesis of claim 1 wherein:

the at least one strand includes a first set of flexible strands spanning substantially the length of the tubular structure, and a second set of flexible strands extending along a first region of the tubular structure to provide a higher axial stiffness and a higher radial force along the first region, and a lower axial stiffness and lower radial force along a second region that does not include the second set of flexible strands; and

one of the first and second regions includes the first and second segments, and the other of said regions includes the third segment.

17. The prosthesis of claim 1 wherein:

the first, second and third segments have substantially the same nominal diameters.

18. The prosthesis of claim 1 wherein:

the first and second segments have respective nominal diameters that are substantially the same, and different than a nominal diameter of the third segment.

19. A body insertable device including:

a body insertable tubular structure including at least one flexible strand selectively formed to define a plurality of discrete tubular regions of the tubular structure including at least a first region and a second region;

wherein each of the regions has a nominal diameter when in a relaxed state and is compressible against an elastic restoring force to a predetermined diameter less than its nominal diameter; and

wherein the at least one strand incorporates a first number of filaments along the first region and incorporates a second number of filaments along the second region, the second number being less than the first number whereby the first region has a first axial stiffness level higher than a second axial stiffness level of the second region.

20. The device of claim 19 wherein:

the at least one strand along the first region incorporates first and second different types of filaments, and the strand along the second region incorporates only the first filament type.

21. The device of claim 20 wherein:

the first filament type is selected from the group of filament types consisting of: metallic filaments and biostable non-metallic filaments; and the second filament type is selected from the group of filament types consisting of: metallic filaments, biostable non-metallic filaments, and biodegradable filaments.

22. The device of claim 19 wherein:

the at least one strand comprises a cable incorporating at least two filaments along the first region.

23. The device of claim 19 wherein:

the tubular structure includes an alternating series of first tubular segments having relatively high axial stiffness levels and second tubular segments having relatively low axial stiffness levels, wherein the first tubular region includes the first tubular segments and the second tubular region includes the second tubular segments.

24. The device of claim 23 wherein:

the tubular structure includes, at first and second opposite ends thereof, end segments selected from the group of end segments consisting of: two first segments; two second segments; and a first segment and a second segment.

25. A prosthesis insertable into body lumens with natural curvature, including:

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a body insertable tubular wall incorporating an alternating sequence of first and second tubular wall segments including at least three of the wall segments, each of the wall segments having a nominal diameter when in a relaxed state and being radially compressible against an elastic restoring force to a predetermined diameter;

wherein the wall segments when radially compressed to the predetermined diameter have respective axial stiffness levels, with each of the first tubular wall segments having a relatively high axial stiffness level, and with each of the second tubular wall segments having an axial stiffness level lower than that of the first tubular wall segments whereby the second tubular wall segments, as compared to the first tubular wall segments, more readily conform to a curvature of a body lumen in which the tubular wall is deployed.

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✓ 26. The prosthesis of claim 25 wherein:

all of the first tubular wall segments have substantially the same axial stiffness, and all of the second tubular wall segments have substantially the same axial stiffness.

✓ 27. The prosthesis of claim 26 wherein:

the body insertable tubular wall is composed of at least one flexible strand selectively formed to provide the alternating first and second tubular wall segments.

✓ 28. The prosthesis of claim 27 wherein:

the at least one flexible strand includes a plurality of flexible strands helically wound in opposite directions to form multiple strand crossings defining strand crossing angles, and wherein the strand crossing angles along the second tubular wall segments are larger than the strand crossing angles along the first tubular wall segments.

✓ 29. The prosthesis of claim 25 wherein:

the tubular wall segments have respective radial force levels when radially compressed to the predetermined diameter, and the radial force levels of the first tubular wall segments are higher than the radial force levels of the second tubular wall segments.

✓ 30. The prosthesis of claim 25 wherein:

the tubular wall segments have respective radial force levels when radially compressed to the predetermined diameter, and the radial force levels of the first tubular wall segments are lower than the radial force levels of the second tubular wall segments.

31. The prosthesis of claim 27 wherein:

the at least one flexible strand incorporates a first number of filaments along each of the first tubular wall segments and a second number of filaments along each second tubular wall segment, wherein the second number is less than the first number.

32. A body insertable stent, including:

a stent structure formed of at least one flexible composite strand and adapted for deployment at a site within a body lumen to apply a radially outward force against surrounding tissue at the site;

wherein the composite strand includes at least one biostable filament and at least one bioabsorbable filament and is adapted to apply the radially outward force initially upon deployment in situ at a first level due to a combination of the at least one biostable filament and the at least one bioabsorbable filament; and

wherein the at least one bioabsorbable filament is absorbable in situ, thereby to reduce the radially outward force toward a second level due to the at least one biostable filament alone.

33. The stent of claim 32 wherein:

the stent structure along its length includes a plurality of discrete regions including a first region along which the at least one strand incorporates the at least one biostable filament and the at least one bioabsorbable filament, and a second region along which the at least one strand incorporates only the at least one biostable filament.

34. The stent of claim 32 wherein:

the at least one composite strand includes a plurality of the biostable filaments, and a plurality of the bioabsorbable filaments.

35. The stent of claim 32 wherein:

the at least one composite strand includes a plurality of the strands helically wound in opposite directions to form multiple strand crossings defining strand crossing angles.

36. The stent of claim 32 wherein:

the at least one biostable filament comprises a non-metallic filament.

① restrict out 37. A process for fabricating a body insertable prosthesis adapted to apply outward radial forces that vary along the prosthesis length, including:

providing at least one flexible, biocompatible and thermally formable strand;

winding the at least one flexible strand onto a substantially constant diameter cylindrical shaping mandrel, and altering a pitch at least once during winding to form a tubular prosthesis structure having a selected shape in which the at least one strand is wound at a first pitch along a first region of the structure, and wound at a second pitch different from the first pitch along a second region of the structure; and

while maintaining the at least one strand in the selected shape, heating the tubular structure to a temperature sufficient to thermally impart the selected shape to the tubular structure.

38. The process of claim 37 wherein:

said winding comprises winding at least first and second flexible strands helically in opposite directions to form multiple intersections of the strands, wherein the intersecting strands define different first and second strand crossing angles along the first and second regions, respectively.

39. The process of claim 37 further including:

after said winding, removing the tubular structure from the shaping mandrel, and placing the tubular structure onto a substantially constant diameter heat-set mandrel; and

wherein said heating the tubular structure comprises heating the heat-set mandrel.

② 40. A process for fabricating a body insertable prosthesis, including:

winding at least one flexible, biocompatible and thermally formable strand onto a substantially constant diameter shaping mandrel at a substantially uniform pitch, to form a tubular structure;

removing the tubular structure from the shaping mandrel, placing the tubular structure onto a heat-set mandrel having a plurality of mandrel segments with different diameters;

causing the tubular structure to conform to the heat-set mandrel and thus assume a selected shape in which the tubular structure has a first region with a first diameter, a second region with a second diameter, and an intermediate region between the first and second regions and having a third diameter outside of a range of diameters bound by the first and second region diameters.; and

with the tubular structure conforming to the heat-set mandrel, heating the heat-set mandrel sufficiently to thermally impart the selected shape to the tubular structure.

41. The process of claim 40 wherein:

the winding of the at least one strand comprises helically winding at least first and second strands in opposite directions to form multiple intersections of the strands.

42. A process for fabricating a body insertable prosthesis, including:

winding at least one flexible, biocompatible and thermally formable strand onto a shaping mandrel having at least a first region with a first diameter and a second region disposed axially of the first region and having a second diameter different than the first diameter, to form a tubular structure having an initial shape;

removing the tubular structure from the shaping mandrel, and disposing the tubular structure along and in surrounding relation to a heat-set mandrel;

causing the tubular structure to substantially conform to the heat-set mandrel, thereby to assume a selected shape; and

with the tubular structure in the selected shape, heating the tubular structure to a temperature sufficient to thermally impart the selected shape to the tubular structure and thereby form in the tubular structure first and second segments corresponding respectively to portions of the tubular structure previously disposed along the first and second regions of the shaping mandrel, said first and second segments being adapted to exert respective first and second different levels of radially outward force when the tubular structure is radially compressed to a predetermined diameter.

43. The process of claim 42 wherein:

the heat-set mandrel has a substantially constant diameter, whereby the tubular structure in the selected shape has a substantially constant diameter.

44. The process of claim 42 wherein:

the heat-set mandrel has first and second heat-set mandrel regions with different diameters corresponding to the first and second regions of the shaping mandrel, whereby the first and second segments of the tubular structure in the selected shape have respective first and second different diameters.

45. A process for fabricating a body insertable prosthesis with segments that differ in axial stiffness and radial force, including:

providing a flexible strand that is a composite of at least two body compatible filaments;
selectively winding the strand to form a tubular structure with a selected shape; and
selectively removing at least one of the filaments from the at least one strand along a predetermined axially extended region of the tubular structure, whereby the tubular structure along the predetermined region has a reduced axial stiffness level and a reduced radial force level as compared to a remaining region of the tubular structure.

46. The process of claim 45 wherein:

selectively winding the strand comprises winding the strand onto a substantially constant diameter shaping mandrel.

47. The process of claim 45 further including:

after selectively winding the strand and while maintaining the tubular structure in the selected shape, heating the tubular structure to a temperature sufficient to thermally impart the selected shape to the tubular structure.

48. The process of claim 45 wherein:

selectively removing at least one of the filaments comprises cutting the at least one filament at a plurality of selected points along the strand to separate a length of the at least one

filament extending along the predetermined region, then removing the separated length of the filament from the tubular structure.

49. The process of claim 45 wherein:

said filaments include at least one first filament having a first melting temperature and at least one second filament having a second melting temperature lower than the first melting temperature; and

wherein removing at least one of the filaments comprises heating the tubular structure at selected points to a temperature lower than the first temperature and higher than the second temperature.

50. The process of claim 49 wherein:

the heating comprises laser ablation of the at least one second filament.

51. The process of claim 50 wherein:

the at least one strand includes at least one substantially insoluble first filament and at least one soluble second filament; and

wherein the removing of at least one of the filaments comprises dissolving the at least one second filament along the selected region.

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